

EXHIBIT 2

Buto, Kathleen

September 12, 2007

Washington, DC

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IN THE CIRCUIT COURT OF
MONTGOMERY COUNTY, ALABAMA

STATE OF ALABAMA,)	
Plaintiff,)	Case No.
vs.)	CV-05-219
ABBOTT LABORATORIES, INC.,)	Judge Charles
et al.,)	Price
Defendants.)	

STATE OF WISCONSIN CIRCUIT COURT
DANE COUNTY

STATE OF WISCONSIN,)	
Plaintiff,)	
vs.)	CASE NO.
AMGEN INC., et al.,)	04-CV-1709
Defendants.)	

Henderson Legal Services
202-220-4158

6d424235-0f61-4f68-bb27-bd89de0f8093

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1 identification.)

2 BY MR. TORBORG:

3 Q. For the record, what I've marked as
4 Exhibit Abbott 298 is a Westlaw printout of
5 certain portions of the proposed rule dated June
6 5th 1991 for fee schedule for physician services.
7 The actual proposed regulation is quite long. I
8 printed out portions that I wanted to ask you
9 some questions about.

10 A. Okay.

11 Q. And I believe you stated earlier that
12 this was an effort, this particular fee schedule
13 regulation, that you were involved in, correct?

14 A. Correct.

15 Q. If I could direct you to the second
16 page of the document that I've handed you. It
17 has page 24 at the top?

18 A. Yes. Mm-hmm.

19 Q. The section under drugs states "The
20 program currently pays for drugs furnished in
21 physician's offices that are not self-
22 administered under the incident 2 provision set

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1 forth in section 1861(S)(2) of the act."

2 And then the next paragraph states "We
3 considered the following options for paying for
4 drugs under the fee schedule: Option 1,
5 establish a fee schedule amount for each drug."
6 And option 2 was "Bundle the payment for the drug
7 into payment for the visit or consultation
8 service."

9 3, "Make a separate payment for a drug
10 and leave the pricing of the drug to each
11 carrier." Option 4, "Make a separate payment for
12 a drug but require a consistent method in pricing
13 to be used by the carriers." Correct?

14 A. Yes.

15 Q. And then below I believe the comments
16 state that option 1 was rejected at least for the
17 time being because it was not practical; is that
18 correct?

19 A. Right.

20 Q. And do you recall that?

21 A. Yes.

22 Q. And there's reference to considering

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1 the issue in the future?

2 A. Mm-hmm.

3 Q. Do you recall whether that was
4 considered in the future?

5 A. I don't think so.

6 Q. Do you know why not?

7 A. The press of other business.

8 Q. Option 2, "Bundle the payment for the
9 drug into the payment for the visit or
10 consultation service," was that --

11 A. Well, actually, let me just amend what
12 I just said. I think the other reason was we
13 were going down a different path in drug
14 reimbursement looking to do at a lower percentage
15 off AWP. So we decided -- we sort of went down
16 that path and didn't go down the other path of
17 trying to compute individual prices for a whole
18 fee schedule for all drugs that Medicare uses at
19 all dosing levels. Just a laborious, labor-
20 intensive effort.

21 Q. In the paragraph under option 4, that
22 next paragraph that starts "We believe," the last

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1 sentence states "Also we are proposing that we
2 will instruct all carriers to base payment for
3 drugs on 85 percent of the national average
4 wholesale price of the drug (as published in the
5 Red Book in and similar price listings), but we
6 welcome comments regarding the appropriate
7 discount."

8 Do you recall receiving comments
9 regarding the appropriate discount?

10 A. I don't. But I am guessing there were
11 comments.

12 Q. Who was responsible for reviewing the
13 public comments that came in to your office as
14 recognition --

15 A. Oh. We had a --

16 Q. For drugs?

17 A. Well, it's for everything. There was a
18 regulation staff and the regulation staff has a
19 fairly systematic way of bringing comments in, as
20 many as forty to ninety thousand comments on
21 certain regulations. So they catalogue them.
22 Log them in, date stamp them.

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1 And they try to categorize them by
2 category in the regulation because different
3 regulations have different staff involvement. So
4 you've got to group them so that the staff who
5 has to look at them has a binder like that
6 (indicating) of the comments they have to review.
7 And that staff, the regulation staff, is the one
8 that pulls all the comments together.

9 I believe the staff was headed up by a
10 woman named Sue Brown, B-r-o-w-n, at the time
11 this regulation was done.

12 Q. In the next paragraph about three-
13 fourths of the way down there's a sentence that
14 starts with "moreover." Do you see that?

15 A. No.

16 Q. I think it's the third, fourth full
17 sentence under the Medicare policy paragraph.

18 A. Fifth from the bottom?

19 Q. Second-to-last sentence from the bottom
20 in the paragraph. "Moreover." It states
21 "Moreover, we are proposing for very high volume
22 drugs the payment for the drug would be limited

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1 to the lower of the estimated acquisition cost of
2 the drug as determined by us and specified in
3 instructions to carriers or 85 percent of the
4 national average wholesale price for the drug."

5 A. Right.

6 Q. What did you mean when you say
7 "national average wholesale price for the drug"?

8 A. AWP.

9 Q. As reflected in Red Book or a similar -

10 -

11 A. Yes, or some other resource.

12 Q. Why did you propose this estimated
13 acquisition cost option for very high volume
14 drugs?

15 A. Because we didn't think that Red Book
16 even a 15 percent discount was an accurate
17 acquisition cost. We wanted to do a survey,
18 actually look at the acquisition cost.

19 Q. You believed that for some drugs the
20 discount might be greater than 15 percent?

21 A. Yes. And we were -- as you can see, we
22 were looking for the low hanging fruit. We were

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1 looking for the high volume drugs where Medicare
2 was probably a dominant payor.

3 (Exhibit Abbott 299 was marked for
4 identification.)

5 BY MR. TORBORG:

6 Q. For the record, what I've marked as
7 Exhibit Abbott 299 is is a document that was I
8 believe collected in counsel's review of public
9 comments maintained by HCFA for this proposed
10 regulation. This particular one comes from the
11 National Medical Care, Inc. organization.

12 A. Right.

13 Q. I have a number of questions for you on
14 this document, but let me start off with a few to
15 start off with. Are you familiar with National
16 Medical Care?

17 A. Yes.

18 Q. And what kind of an organization are
19 they?

20 A. They run for-profit dialysis centers.

21 Q. If you would go to the third page of
22 the document, the last paragraph, NMC wrote "As a

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1 technical matter it should be noted that while in
2 the discussion of the proposal it is clear that
3 HCFA proposes to pay 85 percent of AWP of a drug"
4 -- and this is in italics -- "as published in
5 redbook" -- end italics -- "the actual proposed
6 regulatory language is '85 percent of the
7 national average wholesale price of the drug" --
8 and then in italics -- "as determined by HCFA.'

9 "In the first case, AWP is a category
10 of data of questionable relationship to reality
11 contained in the particular published source. In
12 the second, AWP is empirically determined by HCFA
13 and might in fact be an accurate reflection of
14 prices paid. But certainly HCFA does not propose
15 to pay 85 percent of the actual average
16 acquisition cost - a policy which would result in
17 none of the affected drugs being provided. This
18 inconsistency needs to be eliminated."

19 And if you look back at the document I
20 just showed you, the proposed legislation, on the
21 last page of that exhibit, page 137 at the top,
22 in fact in the payment rule they did -- that is

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1 how you defined AWP in that proposed regulation,
2 correct? I'm under 42 C.F.R. section 415.34,
3 section B, payment rule.

4 A. Okay.

5 Q. It states "Except as specified in
6 paragraph D of this section, payment for drugs
7 furnished incident to a physician's service is
8 limited to 85 percent of the national average
9 wholesale price of the drug as determined by
10 HCFA," correct?

11 A. (Nods head).

12 Q. And that was the language that NMC had
13 pointed out to you as being --

14 A. Yes.

15 (Exhibit Abbott 300 was marked for
16 identification.)

17 MR. DRAYCOTT: With this document we
18 reach another milestone?

19 MR. TORBORG: Yes. Exhibit Abbott 300.
20 BY MR. TORBORG:

21 Q. Ms. Buto, what we've marked as Exhibit
22 Abbott 300 is another comment that was obtained

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1 by counsel in reviewing the public comments at
2 site at HCFA. And I'll ask you some questions
3 about this later. But in later footnote 1 on the
4 fourth page of the document --

5 A. Yes.

6 Q. -- if you would read that. Or I'll
7 read it into the record and you can follow along.

8 A. Is this --

9 Q. This is ASCO's comment to the proposed
10 rule. ASCO wrote "We note an apparent
11 discrepancy between the proposal as discussed in
12 the preamble and the text of the proposed
13 regulation. The preamble refers to the" --
14 underlined -- "published average wholesale price
15 whereas the proposed regulation (section 415.34)
16 refers to the 'national average wholesale price
17 of the drug as determined by HCFA.'

18 "Since the underlying rationale of the
19 proposal is that AWP as published in sources such
20 as the" -- underlined -- "Red Book" -- end
21 underline -- does not reflect the true price, any
22 reference in the regulation must be to" --

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1 underlined -- "published AWP. Insofar as the
2 regulation suggests that HCFA could determine
3 true average wholesale price and then pay only 85
4 percent of that, it is plainly inconsistent with
5 the rationale of the rule."

6 A. Sure sounds like NMC and ASCO were
7 talking with each other.

8 Q. But they had the same criticism,
9 correct?

10 A. Yes.

11 Q. Do you recall discussing that with
12 anyone?

13 A. No. But I agree with them in the
14 interpretation, their interpretation of the
15 inconsistency.

16 (Exhibit Abbott 301 was marked for
17 identification.)

18 BY MR. TORBORG:

19 Q. Ms. Buto, this is a copy of the final
20 rule, excerpts of it that I've printed off
21 Westlaw.

22 A. Mm-hmm.

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1 Q. I've printed off the sections that
2 seemed relevant to reimbursement of drugs because
3 otherwise I would probably kill a number of
4 trees.

5 A. Right.

6 Q. Does this appear to you to be a copy of
7 some of the final rule?

8 A. You know, it's been a long time but I'm
9 going to say it looks familiar.

10 Q. And in the final rule -- if I could ask
11 you to turn to page 56 first under the section
12 payment for drugs --

13 A. Mm-hmm.

14 Q. -- there's a comment that states "We
15 received a great many comments on this issue
16 primarily from oncologists indicating that our 85
17 percent standard was inappropriate. The thrust
18 of most of the comments was that many drugs could
19 be purchased for considerably less than 85
20 percent of AWP, particularly multisource drugs,
21 while others were not discounted.

22 "Other commenters suggested that while

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1 pharmacies and perhaps large practices could
2 receive substantial discounts on their drug
3 purchases, individual physicians could not. The
4 bulk of the comments suggesting alternatives to
5 our proposal indicated that the amounts paid
6 should be based on actual or estimated
7 acquisition costs."

8 And then if we could skip a paragraph
9 and go to the response, the rule states "After
10 considering all the comments on this issue we
11 have decided to modify the proposed policy.
12 Payment for drugs would be based on the lower of
13 the national AWP or the Medicare carrier's
14 estimate of actual acquisition costs.

15 "Since there can be many wholesale
16 prices listed for each drug because of multiple
17 sources for the drug, we are defining the
18 national AWP as the median price for all sources
19 of the generic form of the drug. Estimated
20 acquisition costs would be based on individual
21 carrier estimates of the costs that physicians,
22 or other providers as appropriate, actually pay

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1 for drugs."

2 And in that sentence in your final rule
3 the reference to national AWP was to what?

4 A. Say that again.

5 Q. The reference to the term AWP in this
6 regulation was referring to what?

7 A. Well, it sounds like they're -- I guess
8 the thing that I'm stuck on is that it's defined
9 as a median price for all sources of the generic
10 form of the drug. It doesn't seem to address the
11 brand where there is no generic substitution.
12 The national AWP is a median price for all
13 sources of the generic form of the drug.

14 Q. My question I think was a little
15 simpler one than than.

16 A. Okay. Sorry.

17 Q. What does AWP mean in that language?

18 A. Average wholesale price? Is that what
19 you mean?

20 Q. Yes. Does it refer to the prices in
21 Red Book and other compendia?

22 A. It doesn't seem to.

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1 Q. It does not explicitly there, correct?

2 A. It's not explicitly here.

3 Q. Let's go, if we could to section --
4 page 265 at the end of the document. And if you
5 would also have side by side the proposed rule
6 that we looked at previously --

7 A. Right.

8 Q. Do you have that in front of you?

9 A. Mm-hmm.

10 Q. Under the final rule the methodology
11 section B states "Payment for a drug described in
12 paragraph A of this section is based on the lower
13 of the estimated acquisition cost or the national
14 average wholesale price of the drug," correct?

15 A. Yes.

16 Q. The proposed rule had stated under B,
17 payment rule, "Except as specified in paragraph D
18 of this section, payment for drugs furnished
19 incident to a physician's service is limited to
20 85 percent of the national average wholesale
21 price as determined by HCFA." And it's that "as
22 determined by HCFA" language that NMC and ASCO

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1 had raised an issue with, correct?

2 A. Mm-hmm.

3 Q. And in the final rule you deleted that
4 reference to "as determined by HCFA," correct?

5 A. Correct.

6 Q. And do you know the purpose of that
7 deletion?

8 A. I think we must have -- although I
9 don't really remember this -- agreed with their
10 characterization if the national average
11 wholesale price was our way of computing a more
12 accurate cost then saying that we wanted to pay
13 85 percent of that would be unreasonable.

14 So it seemed to be confusing to match a
15 national average wholesale price that was based
16 on some degree of rigor in developing what the
17 actual cost was and taking only 85 percent of
18 that and reimbursing at that level. So I think
19 that's what we were responding to there in
20 dropping the reference to "as determined by
21 HCFA."

22 Q. If I could ask you to go to page 24 of

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1 the final rule. And I'm referring to the page
2 numbers on my printout, not any particular number
3 in the Federal Register. There's a section that
4 talks and it's subsection F. Do you see that?
5 "Low contrast media (LOCM)"?

6 A. Yes.

7 Q. What is low osmolar contrast media?

8 A. It's -- contrast material is used to do
9 sort of imaging studies. And low osmolar
10 contrast media were developed because some people
11 have a very bad allergic reaction to the more
12 traditional contrast media. So -- and these are
13 called non-ionic contrast media.

14 The issue was -- and I'm just trying to
15 see if this is reflected here. The issue was
16 every patient doesn't need this. It's a lot more
17 expensive. But it's essential for somebody who's
18 allergic to the traditional media. So I'm
19 looking at this to see if this was addressing
20 that issue.

21 (Reading) Okay. This deals with
22 a different issue then. This is really about --

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1 sorry. The situation I was talking about, which
2 is a difference in coverage, if you will, existed
3 more in a hospital setting. This one is trying
4 to establish how you pay for these.

5 Q. And it says "We will pay separately for
6 LOCM if it is used for patients with specified
7 characteristics under the standard methodology
8 for the payment of drugs generally," correct?
9 And those are the provisions we just looked at,
10 correct?

11 A. Right. And the phrase "patients with
12 specified characteristics" -- the meaning of that
13 is we are not paying for it for everybody but
14 we're going to use the standard methodology.

15 Q. And when you -- in the next sentence it
16 appears you summarize the standard methodology
17 for the payment of drugs generally; is that
18 right?

19 A. Yes.

20 Q. And you state "That is, we will base
21 payment on the lower of the estimated actual cost
22 or the published wholesale price of the drug"; is

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1 that right?

2 A. (Nods head).

3 Q. And the word "published" refers to --

4 A. It seems to be a change from the
5 language elsewhere in the final rule where we
6 used the national average wholesale price instead
7 of -- here we're using the published wholesale
8 price.

9 Q. If you go to the second to the last
10 page, page 247 of the document, under section E,
11 you understand that in drafting these regulations
12 typically you perform an impact assessment,
13 correct?

14 A. Yes.

15 Q. This section E discusses effects of
16 separate payment for drugs and states -- I'll
17 skip the first couple sentences and read the
18 sentence that starts with "Under our final
19 policy." It states "Under our final policy
20 carriers will be instructed to base payment for
21 drugs on the lower of the estimated acquisition
22 cost or the national average wholesale price of

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1 the drug as published in the Red Book and similar
2 price listings."

3 Is it fair to say, Ms. Buto, that the
4 intent of CMS in drafting this provision with
5 respect to average wholesale price was to refer
6 to the prices that are found in Red Book and
7 similar price listings?

8 A. Yeah. The intent, though,
9 unfortunately, which was never really achieved,
10 was that was the fallback if the agency couldn't
11 come up with estimated acquisition cost. The
12 agency never really came up with estimated
13 acquisition cost.

14 Q. There were two possibilities for
15 determining the payment amount, one was estimated
16 acquisition cost. If you were not able to find
17 that for a particular drug then it would be
18 reimbursed under the intent of your regulations
19 by virtue of the average wholesale price as
20 published in Red Book and similar price listings,
21 correct?

22 A. Yes. That's certainly the result. The

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1 -- I can't even remember the deliberations and I
2 wouldn't speak of them anyway, as you know. But
3 I do know that our expectation would be that we
4 would be able to do estimated acquisition cost
5 surveys. Unfortunately it didn't work out that
6 way.

7 MR. TORBORG: We're at 5:00. We've
8 probably got to stop for the day.

9 THE WITNESS: Okay. Thank you.

10 THE VIDEOGRAPHER: This concludes tape
11 5 in the deposition of Kathleen Buto. We adjourn
12 for the day at 5:06.

13 (Whereupon, at 5:06 p.m. the
14 deposition was adjourned.)

15
16 _____
17 KATHLEEN BUTO

18 Subscribed and sworn to and before me
19 this _____ day of _____, 20____.

20
21 _____
22 Notary Public

Henderson Legal Services
202-220-4158

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